

Application No. 10/715,221

PVI-5813CIP1CON1
Response to fOA of 01/12/2009**REMARKS**

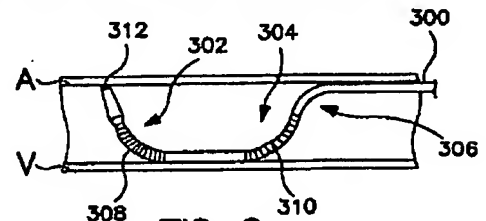
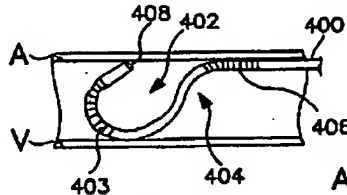
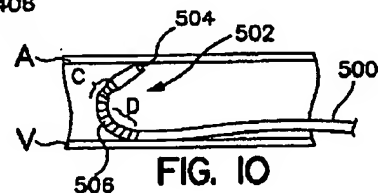
By way of summary, Claims 24, 25, 31–46, and 50–69 were pending in this application, with Claims 25, 35, 39, 41, and 43 being withdrawn from consideration. By this Amendment, Claims 25, 54, and 62 are amended, Claim 69 has been canceled, and Claim 70 has been added; Applicant respectfully submits that no new matter has been introduced by these amendments and that these amendments are made without prejudice or disclaimer. Applicant respectfully reserves the right to pursue the original, previously pending, or canceled subject matter in a continuing application. Accordingly, Claims 24, 25, 31–46, 50–68, and 70 are now pending in this application, and Applicant respectfully requests consideration of the claims in view of the amendments set forth above and the comments provided below.

Rejection under 35 U.S.C. § 102

The Office Action rejected Claims 24, 31–33, 37, 38, 40, 42, 46, 50, 54–57, 59–65, and 67–69 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,321,123, to Morris et al. Applicant respectfully submits that amended independent Claim 24 is patentable over the cited references at least because the cited references do not teach or suggest all the limitations recited in the amended independent claim.

Morris

Morris “relates generally to implantable electrical leads and more particularly for implantable leads intended for use in the coronary sinus of a patient’s heart.” Col. 1:4-6. Described by Morris is an electrical lead that is “pre-formed to display a small radius, J-shaped bend in its distal end.” Col. 1:53-54. “In particular, the J-shaped bend is preferably configured such that the distal tip of the lead is spaced less than about 0.9 inches laterally from

**FIG. 8****FIG. 9****FIG. 10**

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the portion of the lead proximal to the J-shaped bend.” Col. 1:54-57. Morris also describes that “the lead may be implanted with the distal tip of the lead directed distally relatively to the lead body such that the J-shaped bend is opened to display a greater radius of curvature, which also braces the lead within the coronary sinus and stabilizes the location of the tip electrode.” Col. 2:5-10. Exemplary Figures 8-10 are reproduced above for reference.

Applicant respectfully submits that while Morris describes an electrical lead that is inserted into the coronary sinus, Morris fails to teach or suggest an implant that is inserted into the coronary sinus that operates to provide both cardiac rhythm pacing and to reshape tissue adjacent to the coronary sinus and reduce mitral regurgitation. Specifically, Applicant respectfully submits that Morris does not teach or suggest an electrical lead that changes the shape of the tissue outside the vessel into which it is implanted sufficient to reduce mitral regurgitation.

Amended Independent Claim 24

Applicant respectfully submits that amended independent Claim 24 is not anticipated by Morris at least because Morris fails to teach or suggest all the limitations recited in amended independent Claim 24.

For example, amended independent Claim 24 now recites, in part, “the elongate body in the second configuration being configured to exert, while residing completely within the vasculature system, a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus.” As explained above, Applicant respectfully submits that Morris fails to teach or suggest an elongate body that, in the second configuration, is configured to exert, while residing completely within the vasculature system, a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus.

The Office Action stated that the “location of implantation of the device in the claims is seen as functional language . . . and holds no patentable weight in the absence of differentiating structure.” Applicant respectfully submits that Morris fails to provide any teaching or suggestion relating to adjusting or influencing the size of the mitral valve annulus. Applicant further respectfully submits that the amended claim positively recites limitations that implicates differentiating structure. For example, there is no teaching or suggestion in Morris about the electrical lead being able to apply a force against a wall of the coronary sinus sufficient to

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influence the size of the mitral valve annulus. Applicant respectfully submits that the present application is the first disclosure of a device that provides both mitral regurgitation treatment through adjusting the mitral valve annulus and cardiac rhythm pacing through a cardiac pacing electrode on the device.

Applicant respectfully submits that amended Claim 24 is now in condition for allowance over Morris. Moreover, Applicant respectfully submits that the other cited references in the Office Action, U.S. Patent No. 5,879,295, to Li et al., and U.S. Patent No. 6,048,329, to Thompson et al., also fail to teach or suggest any disclosure relating to adjusting the mitral valve annulus. Accordingly, Applicant respectfully submits that amended Claim 24 is in condition for allowance. Applicant, therefore, respectfully requests that the § 102 rejection of Claim 24 be withdrawn.

Amended Independent Claim 54

Applicant respectfully submits that amended independent Claim 54 is not anticipated by Morris at least because Morris fails to teach or suggest all the limitations recited in amended independent Claim 54.

For example, amended independent Claim 54 now recites, in part, “the elongate body in the deployment configuration, when implanted at least partially within the coronary sinus, being configured to apply a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus.” As explained above, Applicant respectfully submits that Morris fails to teach or suggest an elongate body that, in the deployment configuration, is configured to apply a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus.

As explained above, Applicant respectfully submits that the amended claim positively recites limitations that implicate differentiating structure and that there is no teaching or suggestion in Morris about the electrical lead (of Morris) being able to apply a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus. Applicant respectfully submits that the present application provides the first disclosure of a device providing both mitral regurgitation treatment through adjusting the mitral valve annulus and cardiac rhythm pacing through a cardiac pacing electrode on the device.

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Applicant respectfully submits that amended Claim 54 is now in condition for allowance over Morris. Moreover, Applicant respectfully submits that the other cited references in the Office Action, Li and Thompson, also fail to teach or suggest any disclosure relating to adjusting the mitral valve annulus. Accordingly, Applicant respectfully submits that amended Claim 54 is in condition for allowance and respectfully requests that the § 102 rejection of Claim 54 be withdrawn.

Amended Independent Claim 62

Applicant respectfully submits that amended independent Claim 62 is not anticipated by Morris at least because Morris fails to teach or suggest all the limitations recited in amended independent Claim 62.

For example, amended independent Claim 62 now recites, in part, "the elongate body has a best fit curve of constant radius within a range of from about 1.0 cm to about 2.0 cm and is sized and shaped to change a shape of the mitral valve annulus by exerting a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus." Applicant respectfully submits that Morris fails to teach or suggest an elongate body having, in a second shape, a best fit curve of constant radius within a range of from about 1.0 cm to about 2.0 cm and that is sized and shaped to change a shape of the mitral valve annulus by exerting a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus.

As explained above, Applicant respectfully submits that the amended claim positively recites limitations that implicates differentiating structure and that there is no teaching or suggestion in Morris about the electrical lead (of Morris) having a best fit curve of constant radius within a range of from about 1.0 cm to about 2.0 cm or being able to exert a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus. Applicant respectfully submits that the present application provides the first disclosure of a device providing both mitral regurgitation treatment through adjusting the mitral valve annulus and cardiac rhythm pacing through a cardiac pacing electrode on the device.

Applicant respectfully submits that amended Claim 62 is now in condition for allowance over Morris. Moreover, Applicant respectfully submits that the other cited references in the Office Action, Li and Thompson, also fail to teach or suggest any disclosure relating to adjusting the mitral valve annulus. Accordingly, Applicant respectfully submits that amended Claim 62 is

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in condition for allowance and respectfully requests that the § 102 rejection of Claim 62 be withdrawn.

Dependent Claims 31-34, 37, 38, 40, 42, 46, 50, 55-57, 59, 60-61, 63-65, and 67-68

Claims 31-34, 37, 38, 40, 42, 46, 50, 55-57, 59, 60-61, 63-65, and 67-68 were rejected in the Office Action as being anticipated by Morris. These claims depend respectively from amended independent Claims 24, 54, and 62, and Applicant respectfully submits that these dependent claims are allowable for at least the same reasons set forth above with respect to their base amended independent claim, in addition to the independently patentable subject matter recited in each dependent claim. Accordingly, Applicant respectfully submits that these dependent claims are not anticipated by Morris and respectfully requests the rejection of Claims 31-34, 37, 38, 40, 42, 46, 50, 55-57, 59, 60-61, 63-65, and 67-68 under 35 U.S.C. § 102 be withdrawn.

Rejection under 35 U.S.C. § 103

The Office Action rejected dependent Claims 44, 45, and 51-53 under 35 U.S.C. § 103 as being unpatentable over Morris. Applicant respectfully submits that these claims depend from Claim 24 and, as explained above, that Morris fails to teach or suggest all the limitations of at least base Claim 24. Accordingly, Applicant respectfully submits that these claims are patentable for at least the reasons set forth above with respect to their base Claim 24, in addition to the patentable subject matter recited in each of the dependent claims. Accordingly, Applicant respectfully requests withdrawal of the § 103 rejection of Claims 44, 45, and 51-53.

The Office Action rejected dependent Claims 34-36, 58, and 66 under 35 U.S.C. § 103 as being unpatentable over Morris in view of Li. Li was cited by the Office Action for the teaching of a movable lock. However, Claims 34-36, 58, and 66 each depend from amended independent Claims 24, 54, or 62, discussed above. Applicant respectfully submits that Li, alone or in combination with Morris, fails to remedy the inadequate disclosure to render the claims unpatentable discussed above, and Applicant respectfully submits that these claims are in condition for allowance because the cited references, alone or in combination, fail to teach or suggest all the limitations of these dependent claims' base claims, in addition to the independently patentable subject matter recited in each of the dependent claims. Accordingly,

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Applicant respectfully submits that these claims are patentable and respectfully requests withdrawal of the § 103 rejection of Claims 34-36, 58, and 66.

The Office Action rejected dependent Claims 51-53 under 35 U.S.C. § 103 as being unpatentable over Morris in view of Thompson. Thompson was cited by the Office Action for the teaching of materials for an implant. However, Claims 51-53 each depend from amended independent Claims 24, discussed above. Applicant respectfully submits that Thompson, alone or in combination with Morris, fails to remedy the inadequate disclosure to render the claims unpatentable discussed above, and Applicant respectfully submits that these claims are in condition for allowance because the cited references, alone or in combination, fail to teach or suggest all the limitations of Claim 24, in addition to the independently patentable subject matter recited in each of the dependent claims. Accordingly, Applicant respectfully submits that these claims are patentable and respectfully requests withdrawal of the § 103 rejection of Claims 51-53.

New Independent Claim 70

Independent Claim 70 has been added by this Amendment, and Applicant respectfully submits that this independent claim is patentable over the cited references, alone or in combination, at least because the cited references do not teach or suggest all the limitations recited in the new claim. Applicant respectfully submits that no new subject matter has been added to this application by this newly added claim.

New Claim 70 recites, in part, "an elongate body that, when implanted within the coronary sinus of the patient's heart, is configured to exert a force against a wall of the coronary sinus sufficient to influence the size of the mitral valve annulus," and "a cardiac electrode, in or on the elongate body, configured to maintain electrical coupling with a cardiac rhythm management device after implantation of the elongate body in the coronary sinus." Applicant respectfully submits that the cited references do not teach or suggest, alone or in combination, at least these limitations and that new Claim 70 is patentable for at least these reasons over the cited references. Accordingly, Applicant respectfully requests that new Claim 70 be allowed in the next action.

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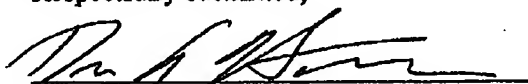
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In view of the foregoing amendments and remarks, Applicant respectfully requests favorable action on this application. If any questions remain, the Examiner is cordially invited to contact the undersigned attorney so that any such matters may be promptly resolved.

Any remarks in support of patentability of one claim should not necessarily be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not necessarily be understood to base patentability on solely that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully reserves the right to traverse any of the Examiner's rejections or assertions, even if not discussed herein. Applicant respectfully reserves the right to challenge later whether any of the cited references are prior art. Although changes to the claims have been made, no acquiescence or estoppel is or should be implied thereby; such amendments are made only to expedite prosecution of the present Application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant reserves the right to contest later whether a proper reason exists to combine prior art references.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-1225 (PVI-5813CIP1CON1) and please credit any excess fees to such deposit account.

Respectfully submitted,

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